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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,215	04/07/2005	Elias Castanas	65321(54558)	1523

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1654

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05/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/522,215	CASTANAS, ELIAS
	Examiner	Art Unit
	David Lukton	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 February 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 28-30,32-50 and 52-59 is/are pending in the application.
- 4a) Of the above claim(s) 34,38-40,42 and 54 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 28,30,32,33,35-37,41,43,48,50,52,53 and 55-59 is/are rejected.
- 7) Claim(s) 29,44-47 and 49 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

Pursuant to the directives of the response filed 2/28/07, claims 28, 48, 52 have been amended; claims 31 and 51 have been cancelled. Claims 28-30, 32-50, 52-59 remain pending.

Claims 28-30, 32, 33, 35-37, 41, 43-50, 52, 53, 55-59 are examined in this Office action; claims 34, 38-40, 42, 54 are withdrawn from consideration.

♦

Claim 28 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 28 of copending application Serial No. 11/398022. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both claims encompass the possibility of treating prostate cancer using a testosterone/albumin conjugate.

[This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented].

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

♦

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it

is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 30, 32, 33, 35, 36, 37, 41, 43, 48, 50, 52, 53, 55-59 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of treating a "haematological malignancy comprising a membrane androgen receptor" and to a method of treating a solid cancer that comprises membrane androgen receptor-bearing tumor cells. At the present time, the examiner is abstaining from making the argument that enablement is lacking for treatment of cancers which comprise membrane androgen receptor-bearing tumor cells.

At the present time, this ground of rejection is directed at the other subgenus, i.e., the method of treating a "haematological malignancy comprising a membrane androgen receptor". The invention is essentially that of treating haematological malignancies that are caused by those aberrant B-cells and T-cells which (according to applicants) bear testosterone receptors, by a method which comprises administering a testosterone conjugate to the affected patient. Even if one makes the assumption that B- and T-cells bear such receptors, the fact is that

all attempts to treat haematological malignancies by administering androgen receptor agonists have resulted in failure.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Accordingly, "undue experimentation" would be required to practice the claimed invention.

♦

Claims 28, 30, 32, 33, 35, 36, 37, 41, 43, 48, 50, 52, 53, 55-59 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The issue raised at this point concerns recitation of the phrase "haematological malignancy comprising a membrane androgen receptor". No doubt there exist some non-hematological tumors which contain cells that bear androgen receptors. But the issue here is whether there is any suggestion in the specification that

leukemia or lymphoma is the direct result of androgen receptor-bearing cells becoming malignant. Applicants are requested to point to the page and line number where this is disclosed.

If applicants cannot point to the page and line number where this is disclosed, the next issue is whether or not it is well known in the art that B- and T-lymphocyte progenitors bear membrane androgen receptors and that agonists thereto are effective to treat leukemia and lymphomas. If applicants believe that this is well known in the art, then it might help applicants' case to provide a few references which convey this. But as matters currently stand, the suggestion that haematological malignancies comprise membrane androgen receptors lacks descriptive support in the specification.

◆

- Claim 30 is objected to. Each of the terms "leukemia" and "leukaemia" are used in the claim. In applicants' opinion, which of these two spellings is correct?
- Claim 44 is objected to for each of two reasons: (a) there should be a hyphen, or at least a space between "testosterone" and "3", and (b) the indefinite article should be present between "thereof" and "composition".

◆

Claims 28 and 48 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 makes reference to a malignancy, wherein the malignancy *per se* comprises a membrane androgen receptor. A "malignancy" is the quality or state of being malignant. While a cell can bear a receptor, a "malignancy" (*per se*) cannot. One option for claim language would be the following (at least insofar as non-hematological malignancies are concerned):

A method of treating cancer in a patient comprising administering to said patient a composition comprising:

(a) one or more androgen steroids and (b) a cytoskeleton-acting drug,

wherein said cancer comprises membrane androgen receptor-bearing tumor cells.

♦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

